



12-09-05
IAP4 Rec'd PCT/PTO 08 DEC 2005
Attorney Docket No.: E3691-00102

In re the Application of)	Group Art Unit: Unknown
)	
Cooper et al.)	Examiner: Unknown
)	
Serial No.: 10/525,345)	Confirmation No.: 3912
)	
Filed: August 20, 2003)	Customer No.: 53897
)	
For: DOSAGE FORMS AND RELATED)	
THERAPIES)	

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97-1.98

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement is being filed prior to the first office action on the merits of the above-captioned application, thus, it is believed that no fee is due in connection with this submission. However, if it is determined that a fee is due, the Commissioner is hereby authorized to charge the requisite fee, or any fees that may be due in connection with this and the attached papers, or with this application during its entire pendency, or to credit any overpayment, to Deposit Account No. 04-1679.

In accordance with 37 C.F.R. §1.56 and 37 C.F.R. §§1.97-1.98, this Information Disclosure Statement, including Forms PTO/SB/08 (12 pages), and cited documents, is provided herewith.

CERTIFICATE OF EXPRESS MAILING UNDER 37 C.F.R. §1.10

I hereby certify that this correspondence (along with any paper referred to as being attached) is being mailed via "Express Mail Post Office to Addressee" service of the United States Postal Service (Express Mail No. EV678345867US and EV678345875US December 8, 2005, in an envelope addressed to the Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450

By: R. P. Ippolito
Roganne Ippolito

Date: December 8, 2005

Applicant would also like to cross-reference the following U.S. and International applications:

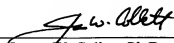
<u>U.S. App. Serial. No.</u>	<u>Filing Date</u>	<u>Pub. No.</u>	<u>Pub. Date</u>
09/671,967	09/27/2000	6,348,465	02/19/2002
09/818,344	03/26/2001	6,855,511	02/15/2005
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11/184,761	07/19/2005	Unknown	Unknown
11/221,298	09/07/2005	Unknown	Unknown

<u>International App. No.</u>	<u>Filing Date</u>	<u>Pub. No.</u>	<u>Pub. Date</u>
PCT/NZ99/00161	09/24/1999	WO 00/18392	04/06/2000
PCT/NZ99/00160	09/24/1999	WO 00/18891	04/06/2000
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PCT/NZ04/000325	12/20/2004		

The items identified in this Information Disclosure Statement may or may not be "material" pursuant to 37 C.F.R. §1.56. The filing of this Information Disclosure Statement is not an admission by Applicants or Applicants' representatives that any of the documents, singly or in any combination, is effective as prior art against the subject application. Additionally, in accordance with 37 C.F.R. §1.97(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists in addition to those submitted herewith.

Applicants respectfully request that the Examiner review the foregoing documents and information and that they be made of record in the file history of the subject application.

Respectfully submitted,

By: 
James W. Collett, Ph.D.
Reg. No. 46,636

DUANE MORRIS LLP
101 West Broadway, Suite 900
San Diego, CA 92101-8285
(O) (619) 744-2200
(F) (619) 744-2201

Substitute Form PTO-1449 (M-Form)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. E3691-00102	Application No. 10/525,345
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Cooper et al.	
		Filing Date 08/20/2003	Group Art Unit Unknown

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(37 CFR § 1.902)

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	3791988	02/12/1974	Josef Dieter			
	AB	4374829	02/22/1983	Harris et al			
	AC	4410541	10/18/1983	Kamimae et al.			
	AD	4758583	07/19/1988	Cerami et al.			
	AE	4866090	09/12/1989	Hoffman et al.			
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	AG	5077313	12/31/1991	Lubec			
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	AM	6147070	11/04/2000	Faccjomo			
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	AO	6610693	08/26/2003	Baker			
	AP	6821954	11/23/2004	Reid et al.			
	AQ	6855511	02/15/2005	Baker			
	AR	6884575	04/26/2005	Cooper et al.			
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	AU	2002/0034775	03/21/2002	Baker, J.R.			
	AV	2003/0045506	03/06/2003	Baker, J.R.			
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	AAA	2004/0023854	02/05/2004	Cooper et al.			

Examiner Signature <i>/June Rogers/</i>	Date Considered 05/27/2008
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Substitute Disclosure Form (PTO-1449)

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(37 CFR §1.98(b))

U.S. Patent Documents							
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	ABB	2004/0038861	02/26/2004	Cooper et al.			
	ACC	2004/0142393	07/22/2004	Cooper et al.			
	ADD	20050002876	01/06/2005	Yukl et al.			
	AEE	2005/0159489	07/21/2005	Baker et al.			
	AFF	2005/0159364	07/21/2005	Cooper et al.			
	AGG	2005/0074756	04/07/2005	Cooper et al.			
	AHH	2005/0047998	03/03/2005	Cooper et al.			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AII	EP 0331014	02/23/1989	Europe				
	AJJ	DE 3217071 A1	11/10/1983	Germany				
	AKK	EP 0426066 A2	05/08/1991	Europe				
	ALL	EP 0 576 838	01/05/1994	Europe				
	AMM	GB 2192789 A	01/27/1988	Europe				
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	AOO	JP 2000204037	07/25/2000	Japan				
	APP	JP 7118148	05/09/1995	Japan				
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	ARR	WO 8201804 A	05/27/1982	WIPO				
	ASS	WO 85/04169	09/26/1985	WIPO				
	ATT	WO 87-05505 A1	09/24/1987	WIPO				
	AUU	WO 95/11690	05/04/1995	WIPO				
	AVV	WO 95/17900	07/06/1995	WIPO				
	AWW	WO 96/12483	05/02/1996	WIPO				
	AXX	WO 9840071 A	09/17/1998	WIPO				
	AYY	WO 99/39712 A1	08/12/1999	WIPO				

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Foreign Patent Documents or Published Foreign Patent Applications

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							Yes	No
	AZZ	WO 9945907 A2	09/16/1999	WIPO				
	AAAA	WO 00/18392 A1	04/06/2000	WIPO				
	ABBB	WO 00/18891 A1	04/06/2000	WIPO				
	ACCC	WO0078805A1	12/28/2000	WIPO				
	ADDD	WO2002079785A2	10/10/2002	WIPO				
	AEEE	WO2003045424A1	06/05/2003	WIPO				
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	AMMM	WO2004012760A1	02/12/2004	WIPO				
	ANNN	WO2004012761A1	02/12/2004	WIPO				
	AOOO	WO2004017956A1	03/04/2004	WIPO				
	APPP	WO2004017957A1	03/04/2004	WIPO				
	AQQQ	WO2004056861 A2	07/08/2004	WIPO				
	ARRR	WO2004065614 A2	08/05/2004	WIPO				
	ASSS	WO2004083215 A1	09/30/2004	WIPO				
	ATTT	WO2004087160 A1	10/14/2004	WIPO				
	AUUU	WO2005058294 A1	06/30/2005	WIPO				
	AVVV	WO2005040205A1	05/06/2005	WIPO				

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Examiner Initial	Desig. ID	Document
	AWWW	American Diabetes Association. (1997). "Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus", Diabetes Care 20:1183

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(37 CFR §1.98(b))			

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AXXX	American Diabetes Association. (1998). "Economic Consequences of Diabetes Mellitus in the U.S. in 1997", <i>Diabetes Care</i> 21(2):296-309
	AYYY	Anaja, (1997). "Diagnostic performance of red cell sorbitol assay in a Nigerian teaching hospital", <i>Clinica Chimica Acta</i> . 262:1
	AZZZ	Baker, et al. (1993). "Mechanism of fructosamine assay: evidence against role of superoxide as intermediate in nitroblue tetrazolium reduction", <i>Clin Chem.</i> 39(12):2460
	AAAAA	Barthelmebs, M. et al. (1990). "L-Dopa and Streptozotocin-Induced Diabetic Nephropathy in Rats", <i>American Journal of Hypertension</i> 3(6) Part 2:72S-74S
	ABBBB	Barthelmebs, M. et al. (1991). "Effects of Dopamine Pro-drugs and Fenoldopam on Glomerular Hyperfiltration in Streptozotocin-Induced Diabetes in Rats", <i>Journal of Cardiovascular Pharmacology</i> 18(2):243-253
	ACCCC	Barthelmebs, M. et al. (1995). "Pathophysiological Role of Dopamine in the Kidney: Effects in Diabetes Mellitus and after Contralateral Nephrectomy", <i>Hypertens. Res.</i> 18(Suppl. 1):S131-S136
	ADDDD	Baynes, J.W. (1991). "Role of Oxidative Stress in Development of Complications in Diabetes", <i>Diabetes</i> 40:405-412
	AEEEE	Boiadzhieva, N. (1990) "The Effect of Dopaminergic Pharmacological Agents on the Pancreatic Islet Apparatus in Rats", <i>Eksp Med Morfol</i> 29(3):20-26. (English abstract)
	AFFFF	Borgstrom, L. et al. (1986). "Pharmacokinetics of N-Acetylcysteine in Man", <i>Eur J Clin Pharmacol</i> 31:217-222
	AGGGG	Chan, P.C. and Bielski, B.H.J. (1974) "Enzyme-catalyzed Free Radical Reactions with nicotinamide Adenine Nucleotides", <i>J Biol Chem</i> 249(4):1317-1319
	AHHHH	Chan, P.C. and Bielski, B.H.J. (1980). "Glyceraldehyde-3-Phosphate Dehydrogenase-catalyzed Chain Oxidation of Reduced Nicotinamide Adenine Dinucleotide by Peroxy radicals", <i>J Biol chem</i> 255(3):874-876
	AIIII	Chaturvedi, N. et al. (1998). "Effect of Lisinopril on Progression of Retinopathy in Normotensive People with Type 1 Diabetes", <i>The Lancet</i> 351:28-31
	AJJJJ	Dahlman, et al., (2000). "Long-term treatment of Wilson's disease with triethylene tetramine dihydrochloride (trientine)", <i>YJM</i> 9=88(9):609-616
	AKKKK	Deckert T. et al. (1978). "Prognosis of Diabetics with Diabetes Onset before the Age of Thirtyone", <i>Diabetologia</i> 14:363-370
	ALLLL	Dubois, R.S. et al. (1970). "Triethylene Teramine Dihydrochloride in Wilson's Disease", <i>Lancet</i> 2(7676):775
	AMMMM	Duchin, K.L. et al. (1988). "Pharmacokinetics of Captopril in Healthy Subjects and in Patients with Cardiovascular Diseases", <i>Clin Pharmacokinetics</i> 14:241-259
	ANNNN	Elstner, E.F. and Heupel, A. (1976). "Inhibition of Nitrite Formation from Hydroxylammonium-chloride: A Simple Assay for Superoxide Dismutase", <i>Anal Biochem</i> 70:616-620
	AOOOO	Epstein, O. and Sherlock, S. (1980). "Triethylene Tetramine Dihydrochloride Toxicity in Primary Biliary Cirrhosis", <i>Gastroenterology</i> 78(6):1442-1445
	APPPP	CHIARA ET AL: "Novel Degradation Pathway of Glycated Amino Acids into Free Fructosamine by a Pseudomonas sp. Soil Strain Extract." <i>JOURNAL OF BIOLOGICAL CHEMISTRY</i> , vol. 270, no. 1, 1995, pages 218-224, XP002189588 ISSN: 218-224
	AQQQQ	Greenman, D. et al. (1996). "Subchronic toxicity of triethylenetetramine dihydrochloride in B6C3F1 mice and F344 rats", <i>Fundam. Appl. Toxicol.</i> 29(2):185-193

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		Applicant Cooper et al.	
		Filing Date 08/20/2003	Group Art Unit Unknown

Information Disclosure Statement
(Use several sheets if necessary)

(37 CFR §1.98(b))

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	ARRRR	Greenstock, C.L. and Ruddock, G.W. (1976). "Determination of superoxide (O ₂ ⁻) Radical Anion Reaction Rates Using Pulse Radiolysis", <i>Int J Radiat Phys Chem</i> 8:367-369
	ASSSS	Halliwell, B. (1976). "An Attempt to Demonstrate a Reaction between Superoxide and Hydrogen Peroxide", <i>FEBS Lett</i> 72(1):8-10
	ATTTT	Halliwell, B. and Gutteridge, J.M.C. (1989). "Free Radicals in Biology and Medicine", Clarendon Press, Oxford, pp. 136-176
	AUUUU	Haslam, R.H. et al. (1980). "Treatment of Wilson's Disease with Triethylene Tetramine Dihydrochloride," <i>Dev Pharmacol Ther</i> 1 (5):318-324
	AVVVV	Holdiness M.R. (1991). "Clinical Pharmacokinetics of N-Acetylcysteine", <i>Clin Pharmacokinet</i> 20(2):123-124
	AWWWV	Horiuchi, T. et al. (1989). "Purification and Properties of Fructosyl-amino Acid Oxidase from <i>Corynebacterium</i> sp. 2-4-1," <i>Agric Biol Chem</i> 53(1):103-110
	AXXXX	Ido, Y. et al. (1996). "Interactions between the Sorbitol Pathway, Non-enzymatic Glycation, and Diabetic Vascular Dysfunction," <i>Nephrol Dial Transplant</i> 11 [Suppl 5]:72-75
	AYYYY	Karlsson, K. and Marklund, S. L. (1987). "Heparin-induced Release of Extracellular Superoxide Dismutase to Human Blood Plasma," <i>Biochem J</i> 242:55-59
	AZZZZ	Kashiwara, N. et al. (1992). "Selective Decreased de novo Synthesis of Glomerular Proteoglycans under the Influence of Reactive Oxygen Species," <i>Proc Natl Acad Sci USA</i> 89:6309-6313
	AAAAAA	Klein, R. et al. (1985). "Retinopathy in Young-onset Diabetic Patients," <i>Diabetes Care</i> 8(4):311-315
	ABBBB	Kodama, H. et al. (1997). "Metabolism of Administered Triethylene Tetramine Dihydrochloride in Humans," <i>Life Sci</i> 61(9):899-907
	ACCCCC	Marklund, S. L. et al. (1982). "Superoxide Dismutase in Extracellular Fluids," <i>Clin Chimica Acta</i> 126:41-51
	ADDDDD	Mattock, M. B. et al. (1998). "Microalbuminuria and Coronary Heart Disease in NIDDM: An Incidence Study," <i>Diabetes</i> 47:1786-1792
	AEEEE	McCord, J. M. and Fridovich, I. (1969). "Superoxide Dismutase: An Enzymic Function for Erythrocyte (Hemocypreine)," <i>J Biol Chem</i> 244(22):6049-6055
	AFFFFF	Misra, H. P. and Fridovich, I. (1972). "The Role of Superoxide Anion in the Autoxidation of Epinephrine and a Simple Assay for Superoxide Dismutase," <i>J Biol Chem</i> 247(10):3170-3175
	AGGGG	Misra, H. P. and Fridovich, I. (1977). "Superoxide Dismutase: 'Positive' Spectrophotometric Assays," <i>Anal Biochem</i> 79:553-560
	AHHHH	Mizobuchi, N. et al. (1993). "Serum Superoxide Dismutase (SOD) Activity in Diabetes Mellitus," <i>Rinsho Byori</i> 41:673-678. (English Abstract)
	AIIII	Mogensen, C. E. and Christensen, C. K. (1984). "Predicting Diabetic Nephropathy in Insulin-dependent Patients," <i>New Eng J Med</i> 311(2):89-93
	AJJJJ	Mogensen, C. E. et al. (1992). "Microalbuminuria in Non-insulin-dependent Diabetes," <i>Clin Nephrol</i> 38 (suppl 1):S28-S38
	AKKKK	Morita J. et al. (1992). "Wilson's disease treatment by triethylene tetramine dihydrochloride (trientine, 2HClO: long-term observations", <i>Dev. Pharmacol. Ther.</i> 19(1):6-9
	ALLLL	Morpurgo, L. et al. (1990). "The Role of Copper in Bovine Serum Amine Oxidase," <i>Biol Metals</i> 3:114-117
	AMMMM	Muchova, J., et al. (1999). "Antioxidant systems in polymorphonuclear leucocytes of type 2 diabetes mellitus", <i>Diabet Med.</i> 16(1):74-78

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(37 CFR §1.98(b))

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	ANNNNN	Muruganandam A. et al. (1994). "ELISA for In Vivo Assessment of Nonenzymatically Glycated Platelet Glutathione Peroxidase", Clin. Biochem. 27(4):293-298
	AOOOOC	Obach, R. et al. (1984). "The Pharmacokinetic Profile of Carbidoa in Dogs," J Pharm Pharmacol 36:415-416
	APPPPP	Palcic, M. M. and Janes, S. M. (1995). "Spectrophotometric Detection of Topa Quinone," Meth Enzymol 258:34-38
	AQQQQC	Pappert, E. J. et al. (1997). "The Stability of Carbidoa in Solution," Movement Disorders 12(4):608-623
	ARRRRR	Picard, S. et al. (1996). "Minimally Oxidised LDL as Estimated by a New Method Increase in Plasma of Type 2 Diabetic Patients with Atherosclerosis of Nephropathy," Diabetes and Metabolism 22(1):25-30
	ASSSSS	Robbins, S. L. et al. (1984). "Pathologic Basis of Disease," 3.sup.rd ed., W. B. Saunders Company: Philadelphia, pp. 991-1061
	ATTTTT	Saeki, H. et al. (1998). "Malignant Syndrome Associated with Disseminated Intravascular Coagulation and a High Level of Amylase in Serum, Followed by Diabetic Coma in an Elderly Patient with Parkinson's Disease during L-Dopa Therapy," Nippon Ronen Igakkai Zasshi 35(2):139-144. (English abstract)
	AUUUUU	Saxena, A. K. et al. (1996). "Purification and Characterization of a Membrane-bound Deglycating Enzyme (1-Deoxyfructosyl Alkyl Amino Acid Oxidase, EC 1.5.3) from a Pseudomonas sp. Soil Strain," J Biol Chem 271(51):32803-32809
	AVVVVV	Siegemund R. et al. "Mode of action of triethylenetetramine dihydrochloride on copper metabolism in Wilson's disease", Acta. Neurol. Scand. 83(6):364-366
	WWWW	Skrha, J. et al. (1996). "Relationship of Oxidative Stress and Fibrinolysis in Diabetes Mellitus", Diabet. Med. 13(9):800-805
	AXXXXX	Smith, P. R. and Thornalley, P. J. (1992). "Mechanism of the Degradation of Non-Enzymatically Glycated Proteins under Physiological Conditions," Eur. J. Biochem. 210:729-739
	AYYYYY	Smith, S. A. and Pogson, C. I. (1977). "Tryptophan and the Control of Plasma Glucose Concentrations in the Rat," Biochem J 168(3):495-506
	AZZZZZ	Somani, B., et al. (1999). "Elimination of superoxide dismutase interference in fructosamine assay", Clin. Biochem. 32(3):185-188
	AAAAAA	Sone, H. et al. (1996). "Inhibition of Hereditary Hepatitis and Liver Tumor Development in Long-Evans Cinnamon Rats by the Copper-Chelating Agent Trientine Dihydrochloride," Hepatology 23(4):764-770
	ABBBBB	Sugimoto, H. et al. (1999). "Advanced glycation end products-cytokine-nitric oxide sequence pathway in the development of diabetic nephropathy: aminoguanidine ameliorates the overexpression of tumour necrosis factor-alpha and inducible nitric oxide synthase in diabetic rat glomeruli", diabetologia 42(7):878-886
	ACCCCC	Talseth, T. (1976). "Studies on Hydralazine," European Journal of Clinical Pharmacology 10(6):395-401
	ADDDDD	Talseth, T. (1977). "Kinetics of Hydralazine Elimination," Clinical Pharmacology Therapeutics 21(6):715-720
	AEEEEEE	Tanabe, R. et al. (1996). "Uptake Mechanism of Trientine by Rat Intestinal Brush-border Membrane Vesicles," J Pharm Pharmacol 48:517-521

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		Applicant Cooper et al.	
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